

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/523,237 03/10/00 BECKER

M GP068-03.CN1

021365
GEN PROBE INCORPORATED
10210 GENETIC CENTER DRIVE
SAN DIEGO CA 92121

HM22/0619

EXAMINER

SHIBUYA, M

ART UNIT	PAPER NUMBER
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1635

DATE MAILED:

06/19/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/523,237	Applicant(s) BECKER ET AL.
	Examiner Mark L. Shibuya	Art Unit 1635
		
<i>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</i>		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). 		
Status		
1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Apr 6, 2001</u>		
2a) <input checked="" type="checkbox"/> This action is FINAL. 2b) <input type="checkbox"/> This action is non-final.		
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
4) <input checked="" type="checkbox"/> Claim(s) <u>422-441</u> is/are pending in the application.		
4a) Of the above, claim(s) _____ is/are withdrawn from consideration.		
5) <input type="checkbox"/> Claim(s) _____ is/are allowed.		
6) <input checked="" type="checkbox"/> Claim(s) <u>422-441</u> is/are rejected.		
7) <input type="checkbox"/> Claim(s) _____ is/are objected to.		
8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.		
Application Papers		
9) <input type="checkbox"/> The specification is objected to by the Examiner.		
10) <input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.		
11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved.		
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119		
13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).		
a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:		
1. <input type="checkbox"/> Certified copies of the priority documents have been received.		
2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.		
3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).		
*See the attached detailed Office action for a list of the certified copies not received.		
14) <input checked="" type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).		
Attachment(s)		
15) <input type="checkbox"/> Notice of References Cited (PTO-892)		
16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		
17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____		
18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____		
19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)		
20) <input type="checkbox"/> Other: _____		

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DETAILED ACTION

Response to Arguments

1. The applicants' response filed 4/6/01, has been considered. Rejections and/or objections not reiterated from the previous office action mailed 1/18/01, are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

Double Patenting

2. Claims 422-441 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 444-465 of copending Application No. 09/565,427. This rejection is maintained for the reasons of record as set forth in the previous Office action.

a. Applicant acknowledges and does not traverse the rejection.

Claim Rejections - 35 U.S.C. § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 422, 427-431, 433-441 are rejected under 35 U.S.C. 102(e) as being anticipated by Van Gemen et al., Patent No. 5,679,553. This rejection is maintained for the reasons of record as set forth in the previous Office action.

a. Applicant argues that the reference of Van Gemen et al. does not suggest modifying primers to include 2'-O-methyl substitutions, and that Van Gemen et al. directs use of detection

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and capture oligonucleotides modified to prevent their degradation by a nuclease in a sample following amplification.

b. Applicant's arguments have been considered but are not deemed persuasive. The claims are drawn to a kit that comprises an oligonucleotide with at least one 2'-O-methyl modification and written instructions for an amplification procedure. Applicant does not argue that Van Gemen et al. fails to disclose an oligonucleotide containing a 2'-O-methyl modification, but does argue that said modified oligonucleotide is not a primer. However, applicant does not point to any structural requirements for a primer of the claimed invention, that the oligonucleotide of Van Gemen et al. does not fulfill. In other words, there is no difference between the modified oligonucleotide as taught by Van Gemen et al. and an oligonucleotide primer of the claimed invention, other than the use to which the modified oligonucleotide will be put. Any 2'-O-methyl containing oligonucleotide, which is known in the art to be complementary to another sequence, could be packaged in applicant's kit for amplification, with instructions for use, and thereby be encompassed by applicant's claims. Something which is old does not become patentable upon the discovery of a new property. MPEP 2112.

Furthermore, the claim limitations of a kit, which is a product, and instructions for amplification, are not given patentable weight. Being in a kit with instructions is not necessary for using the oligonucleotide primers of the claimed invention. Neither the kit, nor the instruction, are disclosed as limitations to the nucleotide sequence or molecular structure of the modified oligonucleotides. One of ordinary skill in the art would understand, based upon the specification,

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that the container of the kit, any other unclaimed reagents in the kit, and the instructions for use, could be thrown away, with only the modified oligonucleotides saved for use in a hybridization of some sort, because the “kit” and the “instructions” are not necessarily or actually employed in a use of the modified oligonucleotides. The “kit” and the “instructions” do not distinguish, imply or change the structure of the claimed primers such that the modified oligonucleotides of Van Gemen et al. could not be used in the claimed invention. Applicant cannot expect to encompass the modified oligonucleotides of Van Gemen et al., or any 2'-O-modified antisense (*i.e.*, complementary) oligonucleotide, simply by claiming them as part of an amplification “kit” with “instructions” for amplification.

The rejection is maintained.

Claim Rejections - 35 U.S.C. § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 423-426 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gemen et al., Patent No. 5,679,553. This rejection is maintained for the reasons of record as set forth in the previous Office action.

a. Applicant argues that the reference of Van Gemen et al. does not disclose or suggest 2'-O-methyl modified primers and that it is the examiner’s “unsupported conclusion that the motivation for these particular limitation would have been routine optimization. If this rejection is to be maintained, the applicants submit that the Examiner needs to present (I) evidence that 2'-O-

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methyl modified primers are suggested by the prior art and (ii) support for why those skilled in the art would have been motivated to make the *specifically claimed modifications*".

b. Applicant's arguments have been considered but are not persuasive. As stated above, applicant does not point to any structural requirements for a primer of the claimed invention, that the oligonucleotide of Van Gemen et al. does not fulfill. In other words, there is no difference between the modified oligonucleotide as taught by Van Gemen et al. and an oligonucleotide primer of the claimed invention, other than the use to which the modified oligonucleotide will be put. Something which is old does not become patentable upon the discovery of a new property. MPEP 2112. Furthermore, Van Gemen et al., at col. 7, lines 34-40, disclose modification of oligonucleotides on "a sufficient number of nucleotides . . . said modification preferably being present on all nucleotides of the oligonucleotide." Therefore there one of ordinary skill in the art would have been motivated to make regions of various lengths of modified oligonucleotides within oligonucleotides that would be indistinguishable from the primers of the claimed invention.

7. Claim 432 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gemen et al., Patent No. 5,679,553 in view of Cruickshank, Patent No. 5091519.

a. Applicant argues that "[a]s discussed above, Van Gemen does not disclose or suggest 2'-O-methyl modified primers and Cruishank has not been relied upon for satisfying this deficiency."

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b. Applicant's arguments have been considered but are not persuasive. As stated above there is no difference between a modified oligonucleotide as taught by Van Gemen et al. and the oligonucleotide primer of the claimed invention, other than the use to which the modified oligonucleotide will be put. Something which is old does not become patentable upon the discovery of a new property. MPEP 2112.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC)*, whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.

11. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technology Center 1600
June 16, 2001



ANDREW WANG
PRIMARY EXAMINER